ABBOTT

Corporate Regulatory Affairs

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August 18, 1999

The Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane Room 1061
Rockville, MD 20857

RE: Draft Guidance on Resolving Scientific Disputes Concerning the Regulation of Medical Devices; Administrative Procedures on Use of the Medical Devices Dispute Resolution Panel
[Docket No. 99D-0239]

Dear Sirs or Madams:

Abbott Laboratories submits the following remarks in response to the Agency's request for comments on the above-named subject and docket. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 56,000 people and serving customers in more than 130 countries.

I. GENERAL REMARKS

A. Abbott generally supports the July 19, 1999 response to this same subject sent to the FDA by the Health Industry Manufacturers Association (HIMA).

B. Since the Agency is receiving numerous comments on this proposal, we suggest a series of public meetings where various opinions, both supporting and dissenting, can be discussed prior to finalizing the guidance document.

II. SPECIFIC COMMENTS

A. Independence. The draft proposal does not assure the independence of the proposed proceedings for the following reasons. First, the Director of CDRH has the ultimate authority for both the initial review and decision as well as the subsequent dispute resolution process. Having been involved with both the original process and then with the later request for dispute resolution, it is doubtful that the director will change or modify Agency decisions from the prior review processes.

Second, the draft proposal should specifically differentiate and limit the involvement of those Agency employees who were involved with the Agency's initial decisions. Future revisions of the draft proposal should specifically recommend the involvement of Agency employees who were not initially involved with prior decisions.

B. Timeliness. The intent of Congress in section 404 of the FDA Modernization Act of 1997 was to create a timely and independent process for product sponsors. As currently proposed the draft allows for as many as 195 days to pass from the start of the process until the end. While this is quite lengthy, the overall process is further complicated by fourteen separate decision points as shown on page A-1 of the draft. With this length of time and the many potential hurdles just to start the process, we recommend a streamlining of the process to meet the intent of Congress.

C. Consistency. The Agency, product sponsors and related parties are all looking to maximize their resources. However, as shown below, sponsors are confronted with nine different dispute processes, each having its own advantages and disadvantages. There should be a set procedure and prescribed courses of action for utilizing these steps. By clarifying the whole process, and not just this one part, all parties can engage in discussions which have known end points and specified outcomes.

DISPUTE PROCESSES

1. Internal Agency review: 21 CFR 10.75.
2. Citizen petition
3. Petition for administration reconsideration
4. Formal evidentiary public hearing
5. Public hearing before a board of inquiry
6. Public hearing before a public advisory committee
7. Public hearing before the FDA Commissioner
8. Regulatory hearing
9. Civil money penalty hearing.

Additionally, the Center for Devices and Radiological Health has another guidance document titled "Medical Device Appeals and Complaints," which also covers dispute resolution. With so many possibilities for resolving differences, we recommend a revision of this draft proposal specifically to clarify its relationship to the existing guidance document and reduce the many steps and decision points shown in the draft. A broader approach to simplifying, defining and adding hierarchies to the many possible steps should also be considered.

D. Joint Development of Guidance Documents. We recommend that the Agency reconsider some of the prior comments received by the Agency with respect to Docket Number 95P-0110: "Guidance Documents; The Food and Drug Administration's Development and Use" published in the Federal Register on March 7, 1996.

Specifically, the Agency should consider the remarks by PhRma (The "Pink Sheet", August 15, 1999) and Abbott (dated June 4, 1996) before viewpoints are solidified in written form. As part of FDAMA sections 404 and 405, we believe that Agency-industry meetings prior to the issuance of draft guidance documents would improve the overall notice and comment process in developing final guidance documents.

III. CLOSING COMMENTS

The proposed guidance should be revised and reissued for additional comment after consultation with industry and trade associations. The draft proposal does not provide for a timely review nor does it allow for an efficient use of resources by the Agency or the sponsor.

With at least nine separate routes for dispute resolution, we believe that a more consolidated, orderly process should be developed. There appears to be a lack of consensus about which courses of action are preferred and what outcomes can be expected.

The Agency should conduct public meetings or sponsor a live telecast to review this proposed draft as well as the existing dispute guidances. In meeting the intent of FDAMA, the FDA should advise sponsors about the preferred methods for resolving disputes, including the expected outcomes, timing and remaining appeals processes, if any.

Yours truly,

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cc: Margaret M. Dotzel (HF-13)
[Docket 95P-0110]